K021174

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510(k) Summary of Safety and Effectiveness
February 7, 2003

1. Submitter

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2. Name of device

Common name: Cardiac Output Monitor
Trade name: ECOM Endotracheal Cardiac Output Monitor
Classification name: Impedance plethysmograph

3. Description of Device

The ECOM (Endotracheal Cardiac Output Monitoring) System consists of an ECOM Endotracheal Tube, which contains the electrodes, an ECOM Monitor, an ECOM Tube Cable, and a Laptop Computer. The ECOM System is used in conjunction with a commercially available arterial pressure (AP) line and 3 surface leads on the patient's chest for R-Wave Detection. The Instructions For Use in Appendix 1 includes pictures of each of these components.

The ECOM System is intended for the continuous monitoring of cardiac output by a specially designed endotracheal tube using the principle of bioimpedance (impedance cardiography). Bioimpedance is based on the principal that all biological tissues, including blood, muscle, bone and fat, have electrical properties. Of these, blood is one of the most electrically conductive. Because arterial blood is pulsatile, changes in blood flow result in changes in electrical conductivity and hence the impedance of the blood to electrical current.

The ECOM System measures impedance by injecting a small alternating electrical current (100kHz, 4.0mA) between a pair of electrodes located on the shaft and cuff of the ECOM Endotracheal Tube. Additional electrodes on the ECOM Endotracheal Tube sense the change of impedance caused by changes of the aortic blood flow.

A proprietary ECOM algorithm is used to calculate ventricular stroke volume (SV) from the impedance and arterial pressure waveforms. The stroke volume is multiplied by the patient's heart rate (HR) to calculate cardiac output (CO) in liters per minute. In addition to these parameters, ECOM displays traces of the impedance waveforms, R-Wave Detection signals, systolic and diastolic arterial pressure.

The ECOM Endotracheal Tube contains seven low profile, flexible electrodes affixed to the cuff and shaft of a Standard Endotracheal Tube. The close proximity of the endotracheal tube balloon cuff in relationship to the ascending aorta provides an optimal location from which to measure impedance changes resulting from aortic blood flow.

The ECOM Endotracheal Tube is provided sterile for single use only. It will be available in 6.0mm to 9.0mm sizes, in 0.5mm increments.

The ECOM Monitor, Laptop Computer, ECOM Tube Cable, Lead Wire, Arterial Pressure Cable. Cord Sets, Power Supply, and Power Conditioner are reusable and provided non-sterile.

4. Intended Use

The ECOM (Endotracheal Cardiac Output Monitoring) System is intended for the monitoring of cardiac output by impedance cardiography while providing airway management by oral intubation with an ECOM Endotracheal Tube. The ECOM System is indicated for use in patients that are expected to be intubated for 24 hours or less and in whom an arterial pressure line is used.

The ECOM System will display the R-Wave Detection and the Impedance Waveforms as well as the patient's Cardiac Output (CO), Stroke Volume (SV), Heart Rate (HR), Systolic and Diastolic Pressure.

5. Devices to which substantial equivalence is claimed

510(k)#	Device	Manufacturer
K972798	Dynemo 3000	Sometec, Inc.
K963183	BioZ	CardioDynamics
K934742	Swan-Ganz	Baxter Healthcare
K870857	ABCOM1	Applied Biometrics

6. Device compared to predicate device

The ECOM System is substantially equivalent to four devices, three of which are currently on the market, all of which were cleared through the 510(k) process. The ECOM System shares the same intended use as all four predicate devices - cardiac output monitoring. The ECOM System shares certain technological features of each predicate device and no new safety and effectiveness questions are raised.

The Swan-Ganz catheter predicate device measures cardiac output using the principle of thermodilution. The catheter is introduced in the venous system (typically in the internal jugular vein) and "floated" through the right heart into the pulmonary artery using an air-filled balloon at the distal tip. The ECOM System would allow for the determination of continuous cardiac output without the risks associated with right heart catheterization. Like the BioZ™ predicate device, the ECOM System measures cardiac output by a bio-impedance method, but takes the measurement at a different anatomical site. The only significant difference in the ECOM System and BioZ™ is that the ECOM System

measures bio-impedance with electrodes placed in the trachea, whereas the BioZ™ measures impedance with electrodes placed on patient's neck and trunk.

The ABCOM 1™ predicate device, like the ECOM System, uses electrodes placed on a standard endotracheal tube to measure the flow of blood through the patient's aorta using ultrasonic doppler, and thus provides a visual display of cardiac output. While both the ABCOM 1™ and the ECOM System use the same anatomical site, the ABCOM-1™ uses an ultrasonic doppler measuring method rather than the bio-impedance method used by the ECOM System and the BioZ™ product.

The Hemosonic predicate device is a transesophageal probe that measures continuous aortic blood flow using ultrasound technology. Conceptually similar to the ECOM System, which is placed in the trachea adjacent to the ascending aorta, the Hemosonic device is placed in the esophagus adjacent to the descending aorta.

In summary, the intended use, patient population, and anatomical site (trachea) of the ECOM System are equivalent to that of the ABCOM 1™, while the energy emitted and received, as well as the electrode design and function are equivalent to that used in the BioZ™ device. The ECOM System also provides continuous cardiac output without the need for right heart catheterization required of the Swan-Ganz flow directed thermodilution catheter. Furthermore, it is conceptually similar to transesophageal ultrasound catheters in that the probe is placed adjacent to the aorta to measure blood flow. Because the ECOM System is based upon well-established technologies (bio-impedance and measuring cardiac output at the trachea) the device does not present any significant new issues of safety or effectiveness.

7. Clinical Performance Data

This study, which was the final step of a three-phase clinical development program, was performed to document the performance of Imagyn's ECOM System. The two earlier phases were necessary to develop an algorithm for clinical applications and to calibrate the algorithm using actual clinical data.

For this study, time matched data for the ECOM System and pulmonary artery catheters were obtained, which provided multiple thermodilution cardiac output measurements.

8. Conclusions drawn from clinical study

Imagyn's ECOM System is a new system for the measurement of CO that has been tested in human subjects. The ECOM System provides a continuous measurement of CO derived from impedance electrodes on an endotracheal tube measurements / supported by information from blood pressure derived from arterial line pressure measurement and has been found to be substantially equivalent at estimating cardiac output as are the predicate non/less invasive devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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APR 2 9 2003

Imagyn Medical Technologies, Inc.
c/o Ms. Julie Powell
Vice President, Quality Assurance / Regulatory Affairs
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Re: K021174
Trade Name: ECOM Endotracheal Cardiac Output Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II (two)
Product Code: DSB
Dated: February 20, 2003
Received: February 21, 2003

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

Warning: The safety of the ECOM Endotracheal tube for more than 24 hours use has not been established. The irregular tracheal cuff surface of the ECOM Endotracheal tube presents a potential for local pressure injury to the trachea. The ECOM Endotracheal tube should not be inserted when a duration of intubation longer than 24 hours can be anticipated.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021174

Device Name: ECOM™ Endotracheal Cardiac Output Monitor

FDA's Statement of the Indications For Use for device:

The ECOM (Endotracheal Cardiac Output Monitoring) System is intended for the monitoring of cardiac output by impedance cardiography while providing airway management by oral intubation with an ECOM Endotracheal Tube. The ECOM System is indicated for use in patients who are expected to be intubated for 24 hours or less and in whom an arterial pressure line is used.

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021174

Prescription Use Only